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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,497

06/27/2002

John C. Reed

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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/030,497	Applicant(s) REED, JOHN C.	
	Examiner HONG SANG	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-117 is/are pending in the application.
- 4a) Of the above claim(s) 111-113 and 115-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-110 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Reed

1. Applicant's response filed on 3/5/2008 is acknowledged. Claims 89-117 are pending. Claims 1-88 have been cancelled. Claims 111-113 and 115-117 have been withdrawn from consideration.
2. Claims 89-110, and 114 are under examination. Due to species election, claims are examined to the extent that BAG-1 gene encodes BAG-1.

Response to Arguments

Claim Rejections - 35 USC § 103

3. The rejection of claims 89-110 and 114 under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Takayama et al. (Cancer Research 1998, 58: 3116-3131, IDS), Noordzij et al. (J. Urology, 1997, 158: 1880-1885) and Sano et al. (US patent NO. 5,665,539, IDS) is maintained.

Applicant's presented same arguments as in the previous response. The new argument is that Froesch et al. describes that BAG-1 is expressed in prostate cancer cells lines and tissue samples but provides no teaching or suggestion that BAG-1 is overexpressed. The post filing reference of Turner discloses the opposite effects of BAG-1 in different cancers, as such a person of ordinary skill in the art at the time the invention was made, could not have been certain about any correlations of BAG-1

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expression with host survival, let alone have a reasonable expectation of success of achieving the claimed method.

Applicant's arguments have been carefully considered but are not persuasive. As indicated in the previous office action, at the time of filing of the instant invention, the general teachings of the art was that BAG-1 is anti-apoptotic and it prolongs cancer cell survival (see Yawata, Tang, Yang and Takayama). Yawata et al. teach that prolonged cell survival introduced by overproduction of BAG-1 strongly enhances peritoneal dissemination of human gastric cancer cells (see abstract). Yawata et al. further disclose that overexpression of BAG1 leads to prolonged cell survival of murine melanoma B16 cells, and this enhanced anti-cell death activity promotes their pulmonary metastasis (see page 2682, lines 1-3). Tang et al. (J. Clin. Oncology, 1999, June, 17(6): 1710-1719, IDS) teach that BAG-1 is overexpressed in the majority of invasive breast carcinomas, and its overexpression may be associated with a shorter disease-free and overall survival (see abstract, Figures 3 and 4). Tang et al. disclose that patients whose tumors expressed BAG-1 tended to have less favorable clinical outcome (see page 1716, last paragraph). Yang et al. (Exp. Cell Res. 1999, Feb., 247: 200-207, IDS) teach that overexpression of BAG1 enhanced the resistance of cervical cells to apoptosis and may play an important role in apoptosis and human cervical carcinogenesis (see abstract). Takayama et al. teach that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo* (see page 3116, right column, 2nd paragraph, lines 5-7). Takayama et al. teach that BAG-1 can be regarded as a candidate proto-oncogene (see page 3117, left column, 3rd paragraph).

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Therefore, in view of the teachings of prior art such as Yawata, Tang, Yang, and Takayama, one of ordinary skill of art would reasonable conclude that the overexpression of BAG-1 protein promotes the cancer cell survival and is correlated with the metastatic potential of tumor cells. Froesch et al. teach that BAG-1 protein (cytosolic BAG protein) is expressed in all 9/9 prostate cancer cell lines and 51/51 archival prostate tumor specimens (see abstract and title). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention and one would have been motivated to determine the level of BAG-1 expression in prostate cancer. compare said level with a reference level, and further correlate said level with the risk of tumor recurrence, tumor spread and survival in view of Froesch, Takayama and the state of the art because Froesch et al. teach that BAG-1 protein is expressed in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, and Takayama and the state of the art teach that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells in vivo and BAG-1 promotes cell survival. One of ordinary skill in the art would have had a reasonable expectation of success to do so because Froesch et al have already successfully detected BAG-1 protein in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, and Takayama and state of art teach that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells in vivo, and BAG-1 protein promotes cell survival. Regarding the post-filing reference of Turner et al., Turner et al. teach that in early stage of breast cancer, the overexpression of BAG-1 predicts long term survival, which is opposite to the results of Tang et al. for invasive breast cancer (see above). Turner's

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results are considered unexpected. However, the instant invention combined the teachings of prior art and obtained predictable results. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Because of these reasons, the rejection is maintained.

Conclusion

4. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
5/19/08

/Christopher H Yaen/
Primary Examiner, Art Unit 1643